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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,646

02/23/2004

Joseph P. Errico

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LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

11/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,646	Applicant(s) ERRICO ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/29/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/29/08 has been entered.

Priority

The benefit claim priority claim filed on 11/26/07 is not being considered because the priority claim was not filed during the time period set forth in 37 CFR 1.78(a). Since this application filed under 35 U.S.C. 111(a) after November 29, 2000, the time period is during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. A petition must be accompanied by (1) the reference required by 35 U.S.C. 120 for priority to the prior filed application, unless previously submitted; (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to:

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Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. The application filed the reference to prior applications on 2/23/04, but failed to indicate the relationship. Applicant perfected the reference to priority on 11/26/07 by establishing relationships to the prior applications, however, this failed to include the required petition with the submittal.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-21 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by both Errico et al. (2004/158325) and Errico et al. (2004/148027).

The applied references have common inventors with the instant application. Based upon the earlier effective U.S. filing date of the references, it constitutes prior art under 35 U.S.C. 102(e). These rejections under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in either reference was derived from the inventor of this application and is thus not the

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invention “by another,” or by an appropriate showing under 37 CFR 1.131. Figs. 51-54 in both references show the invention as claimed.

Claims 1,4,5,10,15,16 are rejected under 35 U.S.C. 102(a) as being anticipated by Grunberg et al. (WO 02/71986). Figs. 4a,4b show apparatus for distracting intervertebral space comprising a shaft within the sides (402,404) with at least two distal extensions (407,409) coupled to the shaft. The distal extensions have a fixed dimension from one another in the same plane, but the intermediate portions of the extensions move toward and separate via the distractor mechanism **416** in the intermediate location. Regarding claim 10, it can be seen the distractor mechanism includes a pin that can move proximally and distally to increase and decrease the separation between the intermediate portions of the extensions to act as a fulcrum. It can also be seen there is a bifurcated trial with two halves **202** coupled to the distal extensions. The examiner is interpreting the claimed elements “bifurcated trial” in this way: two split halves capable of being inserted into the intervertebral space. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. The external shape is capable of “approximating” the external disc shape of the artificial intervertebral disc. Regarding claims 4,5 the trial halves have a smooth outward facing surface, see Fig. 7. Regarding claim 16, there is a control device **414** coupled to the apparatus.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grunberg et al. (WO 02/71986) in view of Baumgartner (5370697). Grunberg et al. is explained above. However, Grunberg et al. fail to teach a dome outer surface on the implant. Baumgartner shows (Fig. 5) a vertebral contact element **44** having a resting shape of a dome convexly extending from an orthopedic device **2**. It would have been obvious to one of ordinary skill in the art to utilize a dome outer surface on the implant as taught by Baumgartner with the apparatus of Grunberg et al. such that it can be placed within the vertebrae's contour.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunberg et al. (WO 02/71986) in view of Ripple et al. (4566466). Grunberg et al. is explained supra. However, Grunberg et al. fail to teach markings for sizing. Ripple et al. teach (Figs. 6,7) markings for sizing a disc to be implanted. It would have been obvious to one of ordinary skill in the art to use markings as taught by Ripple et al. with the apparatus of Grunberg et al. such that the proper implant can be determined for the patient. It is well known in the art to use markings on shafts and would have been obvious to one of ordinary skill in the art to incorporate markings on a shaft of Grunberg et al. It would have been an obvious expedient to modify the dimensions of the disc size, since using 13mm-20mm would only involve routine skill in the art of a surgeon in estimating the intervertebral space and the proper size of the implant to be placed

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therein. One of ordinary skill in the art clearly can optimize the sizes as taught by Ripple or the claimed range of 13-20mm in claim(s) 8 because both apparatus perform the same function of finding the appropriate size for the patient and would have predictable results on filling the space between vertebrae of a patient.

Response to Arguments

Applicant's arguments with respect to claim 1,21 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700

/Brian E Pellegrino/

Primary Examiner, Art Unit 3738